

Definitions for CTCAE Version 3.0

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CATEGORY

The primary organization of CTCAE v3.0 consists of 28 CATEGORIES based on pathophysiology (e.g., ALLERGY/IMMUNOLOGY) and anatomy (e.g., DERMATOLOGY/SKIN).

Adverse Event (AE)

Any unfavorable symptom, sign, or disease (including an abnormal laboratory finding) associated with the use of a medical treatment or procedure that may or may not be considered related to or caused by the medical treatment or procedure.

Supra-ordinate

A supra-ordinate term is located within a CATEGORY and is a grouping term based on disease process, signs, symptoms, or diagnosis. A supra-ordinate term is followed by the word 'Select' and is accompanied by specific AEs that are all related to the supra-ordinate term. Supra-ordinate terms provide clustering and consistent representation of Grade for related AEs. Supra-ordinate terms are not AEs, are not mapped to a MedDRA term and code, cannot be graded and cannot be used for reporting.

Supra-ordinate terms are not AEs, are not mapped to MedDRA, and cannot be used **alone** for reporting an AE. However, some Select AEs are completely non-specific without including at least **some** of the Supra-ordinate wording. Therefore, the NCI instructions for documenting/reporting AEs associated with a Supra-ordinate and Select AE:

- Some Supra-ordinates group specific clinical findings that are distinct and represent a medical/clinical finding. In these situations, document and report only the Select AE. For example:

Supra-ordinate = Conduction abnormality/atrioventricular heart block --Select

*Asystole

*AV Block-First degree

*AV Block-Second degree Mobitz Type I (Wenchebach)

*AV Block-Second degree Mobitz Type II

*AV Block-Third degree (Complete AV block)

*Conduction abnormality NOS

*Sick Sinus Syndrome

*Stokes-Adams Syndrome

*Wolff-Parkinson-White Syndrome

- Correct documentation is 'Asystole'.
- Unnecessary (redundant, but NOT incorrect) documentation is 'Conduction abnormality/atrioventricular heart block --Asystole'.

- Some Supra-ordinates group specific sites, organs, and/or structures that are meaningless **without** the Supra-ordinate. For example similar body sites, organs, structures appear within broad groupings of Fistula, Obstruction, Leak, Perforation, Stenosis within multiple CATEGORIES--GASTROINTESTINAL,

RENAL/GENITOURINARY,
SEXUAL/REPRODUCTIVE FUNCTION.

Example: Supra-ordinate = Fistula, GI--Select

- *Abdomen NOS
- *Anus
- *Biliary tree
- *Colon/cecum/appendix
- *Duodenum
- *Esophagus
- *Gallbladder
- *Ileum
- *Jejunum
- *Oral cavity
- *Pancreas
- *Pharynx
- *Rectum
- *Salivary gland
- *Small bowel NOS
- *Stomach

- Correct documentation is 'Fistula, Abdomen NOS'.
- Incorrect documentation is 'Abdomen NOS'.
- Unnecessary (redundant, but NOT incorrect) documentation is 'Fistula, GI, Abdomen NOS'.

Definitions for CTCAE Version 3.0 (continued)

Select AEs are Adverse Event terms that are related to a single supra-ordinate term. They all use a single grading scale and are mapped to a MedDRA code and term.

1. Some Select AEs are distinct terms that represent specific clinical findings and have meaning without the associated supra-ordinate term.

Supra-ordinate = Conduction abnormality/atrioventricular heart block -- Select

- *Asystole
- *AV Block-First degree
- *AV Block-Second degree Mobitz Type I (Wenchebach)
- *AV Block-Second degree Mobitz Type II
- *AV Block-Third degree (Complete AV block)
- *Conduction abnormality NOS
- *Sick Sinus Syndrome
- *Stokes-Adams Syndrome
- *Wolff-Parkinson-White Syndrome

- Correct documentation is 'Asystole'.
- Unnecessary (redundant, but NOT incorrect) documentation is 'Conduction abnormality/atrioventricular heart block -- Asystole'.

2. Some Select AEs are meaningless **without** the associated supra-ordinate term. Generally, body sites, organs, structures that are listed within broad groupings (e.g., Fistula, Obstruction, Leak, Perforation, Stenosis) within multiple CATEGORIES (e.g., GASTROINTESTINAL, RENAL/GENITOURINARY, SEXUAL/REPRODUCTIVE FUNCTION) must be reported with the supra-ordinate term.

Example: Supra-ordinate = Fistula, GI--Select

- *Abdomen NOS
- *Anus
- *Biliary tree
- *Colon/cecum/appendix
- *Duodenum
- *Esophagus
- *Gallbladder
- *Ileum
- *Jejunum
- *Oral cavity
- *Pancreas
- *Pharynx
- *Rectum
- *Salivary gland
- *Small bowel NOS
- *Stomach

- Correct documentation is 'Fistula, Abdomen NOS'.
- Incorrect documentation is 'Abdomen NOS'.
- Unnecessary (redundant, but NOT incorrect) documentation is 'Fistula, GI, Abdomen NOS'.

Grades (Severity Scale)

CTCAE v3.0 grading is by definition a 5-point scale generally corresponding to mild, moderate, severe, life-threatening, and death. CTCAE v3.0 attempts to present clinically specific language that best describes the event or clinical scenario. All grades are not appropriate for all AEs.

MedDRA Code

MedDRA (Medical Dictionary for Regulatory Activities) terminology is the standard language for drug regulatory reporting globally. To facilitate data transfer to the FDA and other regulatory agencies, NCI has mapped, wherever possible, all CTCAE v3.0 terms to MedDRA.

Each CTCAE v3.0 term is associated with a unique 8-digit code that is used for database exchange and data analysis.